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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,781	06/11/2001	Alexandra J. Bolton	9000-0055	1484

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COOLEY GODWARD, LLP
3000 EL CAMINO REAL
5 PALO ALTO SQUARE
PALO ALTO, CA 94306

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/878,781

Applicant(s)
Bolton et al.

Examiner
S. Devi, Ph.D.

Art. Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 10, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Restriction

- 1) Claims 1-77 are pending in the application and are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 2, 52 and 53, drawn to a GapC protein of *S. dysgalactiae* comprising amino acids 1-336 of SEQ ID NO: 4, a vaccine and a kit comprising the same, classified in class 530, subclass 350
 2. Claims 3, 54 and 55, drawn to a GapC protein of *S. agalactiae* comprising amino acids 1-336 of SEQ ID NO: 6, a vaccine and a kit comprising the same, classified in class 530, subclass 350
 3. Claims 4, 56 and 57, drawn to a GapC protein of *S. uberis* comprising amino acids 1-336 of SEQ ID NO: 8, a vaccine and a kit comprising the same, classified in class 530, subclass 350
 4. Claims 5, 58 and 59, drawn to a GapC protein of *S. parauberis* comprising amino acids 1-336 of SEQ ID NO: 10, a vaccine and a kit comprising the same, classified in class 530, subclass 350
 5. Claims 6, 60 and 61, drawn to a GapC protein of *S. iniae* comprising amino acids 1-336 of SEQ ID NO: 12, a vaccine and a kit comprising the same, classified in class 530, subclass 350
 6. Claims 8, 9, 19, 20, 30 and 31, drawn to a polynucleotide having nucleotides 1-336 of SEQ ID NO: 3, a vector and a host cell comprising the same, classified in class 536, subclass 23.7

7. Claims 10, 11, 21, 22, 32 and 33, drawn to a polynucleotide containing nucleotides 1-336 of SEQ ID NO: 5, a vector and a host cell comprising the same, classified in class 536, subclass 23.7
8. Claims 12, 13, 23, 24, 34 and 35, drawn to a polynucleotide containing nucleotides 1-336 of SEQ ID NO: 7, a vector and a host cell comprising the same, classified in class 536, subclass 23.7
9. Claims 14, 15, 25, 26, 36 and 37, drawn to a polynucleotide containing nucleotides 1-336 of SEQ ID NO: 9, a vector and a host cell comprising the same, classified in class 536, subclass 23.7
10. Claims 16, 17, 27, 28, 38 and 39, drawn to a polynucleotide containing nucleotides 1-336 of SEQ ID NO: 10, a vector and a host cell comprising the same, classified in class 536, subclass 23.7.
11. Claims 70-72, drawn to antibodies directed to a GapC protein of SEQ ID NO: 4, classified in class 530, subclass 387.9
12. Claims 70-72, drawn to antibodies directed to a GapC protein of SEQ ID NO: 6, classified in class 530, subclass 387.9
13. Claims 70-72, drawn to antibodies directed to a GapC protein of SEQ ID NO: 8, classified in class 530, subclass 37.9
14. Claims 70-72, drawn to antibodies directed to a GapC protein of SEQ ID NO: 10, classified in class 530, subclass 387.9
15. Claims 70-72, drawn to antibodies directed to a GapC protein of SEQ ID NO: 12, classified in class 530, subclass 387.9
16. Claims 41 and 42, drawn to a method of using a host cell comprising SEQ ID NO: 3 to produce a protein, classified in class 435, subclass 71.1
17. Claims 43 and 44, drawn to a method of using a host cell comprising SEQ ID NO: 5 to produce a protein, classified in class 435, subclass 71.1
18. Claims 45 and 46, drawn to a method of using a host cell comprising SEQ ID NO: 7 to produce a protein, classified in class 435, subclass 71.1
19. Claims 47 and 48, drawn to a method of using a host cell comprising SEQ ID NO:

- 9 to produce a protein, classified in class 435, subclass 71.1
20. Claims 49 and 50, drawn to a method of using a host cell comprising SEQ ID NO: 11 to produce a protein, classified in class 435, subclass 71.1
21. Claims 67-69, drawn to a method of treating by administering a polynucleotide of SEQ ID NO: 3, classified in class 424, subclass 184.1
22. Claims 67-69, drawn to a method of treating by administering a polynucleotide of SEQ ID NO: 5, classified in class 424, subclass 184.1
23. Claims 67-69, drawn to a method of treating by administering a polynucleotide of SEQ ID NO: 7, classified in class 424, subclass 184.1
24. Claims 67-69, drawn to a method of treating by administering a polynucleotide of SEQ ID NO: 9, classified in class 424, subclass 184.1
25. Claims 67-69, drawn to a method of treating by administering a polynucleotide of SEQ ID NO: 11, classified in class 424, subclass 184.1
26. Claim 74, drawn to a method of detecting *Streptococcus* antibodies using a GapC protein of SEQ ID NO: 4, classified in class 435, subclass 7.1
27. Claim 74, drawn to a method of detecting *Streptococcus* antibodies using a GapC protein of SEQ ID NO: 6, classified in class 435, subclass 7.1
28. Claim 74, drawn to a method of detecting *Streptococcus* antibodies using a GapC protein of SEQ ID NO: 8, classified in class 435, subclass 7.1
29. Claim 74, drawn to a method of detecting *Streptococcus* antibodies using a GapC protein of SEQ ID NO: 10, classified in class 435, subclass 7.1
30. Claim 74, drawn to a method of detecting *Streptococcus* antibodies using a GapC protein of SEQ ID NO: 12, classified in class 435, subclass 7.1
31. Claim 63, drawn to a method of producing a vaccine by providing a GapC protein, classified in class ???, subclass
32. Claims 64-66, drawn a method of treating an infection by administering a vaccine comprising SEQ ID NO: 4, classified in class 424, subclass 244.1
33. Claims 64-66, drawn a method of treating an infection by administering a vaccine comprising SEQ ID NO: 6, classified in class 424, subclass 244.1

- 34. Claims 64-66, drawn a method of treating an infection by administering a vaccine comprising SEQ ID NO: 8, classified in class 424, subclass 244.1
- 35. Claims 64-66, drawn a method of treating an infection by administering a vaccine comprising SEQ ID NO: 10, classified in class 424, subclass 244.1
- 36. Claims 64-66, drawn a method of treating an infection by administering a vaccine comprising SEQ ID NO: 12, classified in class 424, subclass 244.1

Claims 1, 51, 62, 76 and 77 are considered as linking claims and would be joined with one of inventions 1-5, if elected.

Claims 7, 18 and 29 are considered as a linking claim and would be joined with one of inventions 6-10, if elected.

Claim 40 is considered a linking claim and would be joined with one of inventions 16-20, if elected.

Claim 73 is considered a linking claim and would be joined with one of inventions 26-30, if elected.

4) Inventions 1 through 36 are distinct from one another. Inventions 1-5, 6-10 and 11-15 are drawn to three distinct biological products: proteins, polynucleotides and antibodies, which differ from one another structurally, biologically and immunogenically. Each protein and each polynucleotide is distinct from the other structurally as indicated by their sequences. Similarly, antibody to each protein is distinct from the other in its immunospecificity. Each of these products requires a separate and non-coextensive sequence search. Furthermore, the various methods differ from one another in method steps, parameters, reagents or compositions used and ultimate goals accomplished.

5) Inventions 1-5 and inventions 26-30 and 32-36; inventions 6-10 and inventions 11-20; and inventions 6-10 and inventions 21-25, respectively, are related as products and processes of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the protein products of inventions 1-5 can be used in a materially different process, for example, in research studies to study their

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properties, such as, physicochemical properties, toxicity, enzymatic activity, and/or structural similarity with proteins, or as an immunogen to elicit specific antibody reagents. Similarly, the host cells of inventions 6-10 can be used in a materially different process, for example, a diagnostic *in vitro* assay as coating antigens.

It is noted that the products of inventions 1-5 are not required to practice the methods of inventions 21-25 and 16-20, and the products of inventions 6-10 are not required to practice the methods of inventions 26-30 and 32-36. Similarly, the products of inventions 11-20 are not required to practice the methods of inventions 16-20, 21-25, 26-30 and 32-36.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

6) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

7) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

8) Applicants are asked to note that upon election of claim(s) drawn to a product, the corresponding method of use claim(s) will be retained as pending claims pursuant to the rejoinder provisions of M.P.E.P. 821.04 and will be withdrawn from consideration until such time as the subject matter of elected product claim(s) are deemed allowable. The Examiner in charge of the instant application will then determine if corresponding method claims include all of the limitations of the allowable product claim(s) prior to determining if rejoinder will be permitted under M.P.E.P. 821.04.

9) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on


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Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER